

REMARKS/ARGUMENTS

Claims 1-52 are pending in the application. Claim 52 is new. Claims 1-7, 12, 22-24, 39-40 and 51 have been amended. No new matter has been added. Reconsideration of the claims is respectfully requested.

In paragraph 1 on page 2 of the Office Action, claim 22 are rejected under 35 U.S.C. § 112 second paragraph for being indefinite. The Applicants respectfully traverse this rejection, but have amended the application to overcome the objection. Claim 22 has been amended. It is believed that the claim 22 is in compliance with 35 U.S.C. § 112.

In paragraph 2 on page 2 of the Office Action, claims 1, 7, 12, 13, 23, 31 and 45 are rejected under 35 U.S.C. §102 (b) as being anticipated by Caro (US Patent No. 5348003).

In paragraph 3 on page 3 of the Office Action, claims 2-5, 14-22, 35-38, 41, 48 and 50 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro (US Patent No. 5348003) in view of McLanson et al. (US Patent No. 5800373). The Applicants respectfully traverse this rejection, but have amended the application to overcome the objections.

In paragraph 4 on page 3 of the Office Action, claims 6, 10, 11 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro (US Patent No. 5348003) in view of

Eppstein et al. (US Patent No. 5458140). The Applicants respectfully traverse this rejection, but have amended the application to overcome the objections.

In paragraph 5 on page 4 of the Office Action, claims 8 and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro (US Patent No. 5348003) in view of McLanson et al. (US Patent No. 5800373) as applied to 2-5, 14-22, 36-38 and 41 above, and further in view of Cozzette et al. (US Patent No. 5063081). The Applicants respectfully traverse this rejection, but have amended the application to overcome the objections.

In paragraph 6 on page 4 of the Office Action, claims 24-30, 46 and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro (US Patent No. 5348003) in view of Eppstein et al. (US Patent No. 5885211). The Applicants respectfully traverse this rejection, but have amended the application to overcome the objections.

In paragraph 7 on page 4 of the Office Action, claims 33 and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro (US Patent No. 5348003) in view of Chick et al. (US Patent No. 6040194). The Applicants respectfully traverse this rejection, but have amended the application to overcome the objections.

In paragraph 8 on page 5 of the Office Action, claims 42-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Caro (US Patent No. 5348003) in view of McLanson as applied to claims 2-5, 14-22, 35-38, 41, 48 and 50 above, and further in view of

McAleer et. al. (US Patent No. 5708247). The Applicants respectfully traverse this rejection, but in some cases, have amended the application to overcome the objections.

As claims 39, 40 and 51 were considered allowable if made independent, these claims are now in condition for allowance

Turning to the cited art, the primary reference Caro, this document discloses the measurement of electromagnetic energy absorption in tissue. In one embodiment light is passed thru tissue to measure chemical reactions in tissue and determine certain characteristics of the tissue or fluids therein. This is a totally non-invasive technique.

The present invention is entirely different device and system. First, the present invention is a minimally invasive system meaning that there must be poration of the tissue layer. Caro is a non-invasive system. Therefore, from the start Caro is not applicable as a direct reference and further, as a teaching of the concept since it is based on fully non-invasive techniques, it *teach away* from poration. Without the fundamental concept of poration in Caro, it is difficult to comprehend how it can be used as a primary reference against the claims as now amended. Claim 1, for example, recites an integrated device which accomplishes multiple functions with fluid transporting layer adjacent said tissue contacting layer and aligned with the target portion, said target capable of receiving electromagnetic energy and converting it into thermal energy for tissue poration. None of the cited references have recognized the concept of an integrated device which has these features.

In claims 2 and 3, the addition of a primer and dyes or pigments is recognized by the examiner and not found in Caro or McLanson. McLanson is put forth as being a sufficient teaching of such elements because it uses a primer for adhering to a substrate, but this is not the use to which the primer, dyes or pigments is used. McLanson makes no suggestion of how it converts such elements in to thermal energy.

In claim 5, the concept of a lasers (one form of electromagnetic energy) for *indirect* poration of tissue is introduced. Note that direct poration by laser has proved a dismal failure because of the difficulty if not impossibility to porate tissue painlessly by direct application of laser energy. But, by conversion of such energy into thermal energy and by establishing a target area for conversion, in a single integrated device, it is possible to precisely control the effect of the laser energy. Furthermore, by placing a detection layer having an electro-chemical biosensor which is responsive to the fluids received from the tissue (claim 6) in such a way as to be responsive to the fluid flow, the single integrated device can porate and sense fluids. This is a significant breakthrough since the amount of fluid collected by (micro) poration is necessarily small and by having the bio sensor located in the detection layer of the integrated device, the fluid required to achieve an accurate measurement is vastly smaller than if the sensor was not integral to the poration and collection assembly.

Likewise, for the reasons set forth for claim 1, the method in claim 12, as amended is not anticipated nor rendered obvious by Caro, the only reference applied by the examiner.

Claim 23, recites a heat generating probe which is integral to the device. Clearly the Caro disclosure (the only reference applied to claim 23) is inapplicable as it is totally non-invasive. Furthermore, the non-invasive technique of Caro would hardly be a teaching of having a heat generating probe for the explicit purpose of tissue poration.

Claim 48 was rejected on the basis of Caro in view of Mclanson. Again, the problem with this rejection is that Caro does not function as a sufficient base reference to make the combination under sec 103. As mentioned, Caro lacks the invasive concept of poration, by any means, so combining it with other references does not achieve the present claim nor even provide a basis for a further combination. Furthermore, the heated probe for poration teaches away from the non-invasive technique of Caro.

Claim 50 was rejected on the same basis as claim 48 and for like reasons, the rejection using Carol and Mclanson cannot be sustained.

Finally, new claim 52, which is similar to other independent claims, calls for an integrated tissue contacting layer having a hole thru which a porator which can open the tissue and allow fluid to flow to the detecting layer. The prior cite does not disclose such an integrated device and the base reference, Caro, is a teaching away therefrom by disclosing a non-invasive technique. In the present invention, providing a layer with a hole for poration and a detecting layer adjacent thereto provides an efficient way to collect small amounts of fluid regardless of the means for poration.

The remaining dependent claims, which are dependent from independent claims, were also rejected under 35 U.S.C. §103(a). While Applicants do not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, it is submitted that the dependent claims are also in condition for allowance.

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicant respectfully requests favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicant's attorney of record, Michael B. Lasky at (952) 253-4106.

Respectfully submitted,

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